



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2088 Galter Road
Rockville MD 20850

M 940N

HFI-55

WARNING LETTER

MAY 23 1997

Frank R. Lowry, M.D.
Lowry Ophthalmology
1422 E. Millbrook Road
Raleigh, North Carolina 27609

Dear Dr. Lowry:

The Food and Drug Administration (FDA) inspected your medical practice on April 30, 1997, and determined that you collaborated with Edward Sullivan, an engineering consultant with Esull, Drexel Hill, Pennsylvania, to manufacture an excimer laser system, which is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). Excimer laser systems are Class III devices which are required to have in effect an approved application for premarket approval (PMA) or an approved Investigational Device Exemption (IDE).

Medical devices used by physicians in the course of their practice to treat patients are "marketed" and "held for sale" within the meaning of the Act, and thus, are subject to the provisions of the Act. Your excimer laser system is adulterated under section 501(f)(1)(B) of the Act because it is a Class III device under section 513(f), which is required to have in effect an approved application for PMA or an approved IDE, and no such PMA or IDE is in effect for it. Further, your continued use of this device to treat patients is also a violation of the Act.

Your excimer laser system is not in compliance with Title 21 of the Code of Federal Regulations, (CFR) part 1002.10 because a Laser Product Report has not been received from you yet. In addition, your excimer laser system must comply with the requirements of the Federal performance standards for lasers which are found in 21 CFR parts 1040.10 and 1040.11.

Although your excimer was purportedly manufactured, in part, based upon your specifications, FDA does not consider it to be a custom device. Section 520(b) of the Act establishes five conditions, each of which must be met by a device to be a custom device. The Act's custom device definition requires that the device be made to meet either the specific anatomical requirements of an individual patient or the special needs of an individual practitioner; a practitioner's special needs may be either an individual anatomical need or a special practice need that is not shared by other physicians.

We do not believe the requirements of your medical practice are unique because they are shared by numerous other health professionals. In addition, we do not believe your device is designed to meet any special anatomical needs that you or an individual patient

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of yours may have. Accordingly, your laser is not a custom device and is not exempt from the requirement under the Act that this device must have an approved PMA or IDE in effect.

Please notify this office within 15 working days of your receipt of this letter as to what, if any, actions you are taking or plan to take to bring your device into compliance with the Act. Your response should also clearly state whether or not you have ceased using the device to treat patients. Failure to immediately and completely cease clinical use of the device upon receipt of this letter and failure to bring your device into compliance with the Act, may result in regulatory action by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Please note that no extensions of the 15 day response period will be given.

Your response should be sent to the attention of Mary-Lou Davis, Dental, ENT and Ophthalmic Devices Branch (HFZ-331) at the letterhead address. In addition, please send a copy of your response to Phil Campbell, Compliance Officer, Food and Drug Administration, 60 - Eighth Street, N.E., Atlanta Georgia 30309. If you have further questions, please contact Mary-Lou Davis at (301) 594-4613 extension 127 or FAX: (301) 594-4638.

Sincerely yours,

Casper E. Uderick for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health